ppq.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,577	03/15/2001	Menachem Levanoni	YOR920010163US1	5893

21254 7590 12/31/2003

MCGINN & GIBB, PLLC
8321 OLD COURTHOUSE ROAD
SUITE 200
VIENNA, VA 22182-3817

EXAMINER	
PHAM, THOMAS K	
ART UNIT	**PAPER NUMBER**
2121	8

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

P29

Office Action Summary	Application No.	Applicant(s)
	09/809,577	LEVANONI ET AL.
	Examiner	**Art Unit**
	Thomas K Pham	2121

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. This action is in response to request for re-consideration filed on 10/9/2003

2. New claims 12-21 filed by the applicant has been entered.

3. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

DETAILED ACTION

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-2, 10-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al U.S. Patent No. 4,936,862 (hereinafter Walker) in view of Stark et al. U.S. Patent No. 6,540,707 (hereinafter Stark) and further in view of Larsen U.S. Patent No. 5,050,618.

Regarding claim 1

Walker teaches a computerized method to design a human joint to do at least one of designing, constructing, and adjusting an orthodic for an individual (abstract) comprising: creating a virtual human joint for an orthodic (col. 3 lines 16-20, "the process provides … to duplicate it") for support and comfort but does not teach providing pressure and acceleration sensors; mounting said sensors in a joint-enclosing device; transmitting the data produced by said sensors during actual operation of said joint-enclosing device worn by a specific individual; receiving said

sensor signals for analysis by a computer; creating a stress-and-acceleration map based on said sensor-based data. However, Stark teaches a computerized method that providing pressure (col. 3 lines 9-10, "a pressure sensor ... bladder is measured") and acceleration (col. 9 lines 10-11, "accelerometer 160 ... on the orthosis") sensors; mounting said sensors in a joint-enclosing device (col. 9 line 16, "an accelerometer 160 connected to the knee brace"); transmitting the data produced by said sensors during actual operation of said joint-enclosing device worn by a specific individual (col. 9 lines 15-22, "an accelerometer 160 ... impaired patients"); receiving said sensor signals for analysis by a computer (col. 3 lines 10-15, "a microprocessor receiving ... predetermined target values"). Furthermore, Larsen teaches a computerized method for creating a stress-strain loop at extremes of the range of motion based on said sensor-based data (col. 3 lines 3-12, "Strain gauges are provided ... acceleration of the joint"). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the computerize analysis using sensors of Stark with the computerized constructing method of Walker because it would provide for collecting information in support of a hinge joint or at least one vertebra. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the process of creating a stress-strain loop of Larsen with the computerized constructing method of Walker because it would provide for analyzing and evaluating the elastic component of joint stiffness to create the orthodic model based on the stress-strain loop.

Regarding claim 2

Stark teaches using at least one of temperature, moisture, and skin conductivity sensors which are correlated with a worn orthodic (col. 2 lines 54-57, "Bladders spread the forces ... injury to the skin").

Regarding claim 10

Walker teaches the design of the virtual human joint for an orthodic. Stark teaches optimizing techniques subject to internal or external constraints (col. 5 lines 22-31).

Regarding claim 11

Walker teaches a program storage device readable by a machine, tangibly embodying a program of instructions executable by the machine to design a human joint to do at least one of designing, constructing, and adjusting an orthodic for an individual (abstract), the method comprising: receiving sensor data from pressure and acceleration sensors mounted on a joint-enclosing device worn by a user (col. 3 lines 10-15); creating a virtual human joint for an orthodic (col. 3 lines 16-20, "the process provides ... to duplicate it") for support and comfort but does not teach creating a stress-and-acceleration map based on said sensor-based data. However, Larsen teaches a computerized method for creating a stress-strain loop at extremes of the range of motion based on said sensor-based data (col. 3 lines 3-12, "Strain gauges are provided ... acceleration of the joint"). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the process of creating a stress-strain loop of Larsen with the computerized constructing method of Walker because it would provide for analyzing and evaluating the elastic component of joint stiffness to create the orthodic model based on the stress-strain loop.

Regarding claim 12

Walker teaches at least one of: constructing a physical orthodic based on the virtual human joint, and adjusting a physical orthodic based on the virtual human joint (col. 3 lines 7-20, "The resulting computer … to duplicate it").

Regarding claim 13

Walker teaches using data from the virtual human joint for an orthodic to construct a physical orthodic (col. 3 lines 16-20, "the process provides … to duplicate it").

Regarding claims 14 and 21

Walker teaches a computerized method to design a human joint to do at least one of designing, constructing, and adjusting an orthodic for an individual (abstract) but does not teach receiving, in a computer, data from pressure and acceleration sensors mounted on a joint-enclosing device worn by a user; and generating a stress-and-acceleration map from said data. However, Stark teaches receiving, in a computer, data from pressure and acceleration sensors (col. 3 lines 10-15, "a microprocessor receiving … predetermined target values") mounted on a joint-enclosing device worn by a user (col. 9 lines 15-22, "an accelerometer 160 … impaired patients"). Furthermore, Larsen teaches a computerized method for creating a stress-strain loop at extremes of the range of motion based on said sensor-based data (col. 3 lines 3-12, "Strain gauges are provided … acceleration of the joint"). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the computerize analysis using sensors of Stark with the computerized constructing method of Walker because it would provide for collecting information in support of a hinge joint or at least one vertebra. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the process of creating a stress-strain loop of Larsen with the computerized constructing

method of Walker because it would provide for analyzing and evaluating the elastic component of joint stiffness to create the orthodic model based on the stress-strain loop.

Regarding claim 15

Walker teaches calculating a virtual human joint model (abstract) but does not teach the stress- and acceleration map. However, Larsen teaches a computerized method for creating a stress-strain loop at extremes of the range of motion based on said sensor-based data (col. 3 lines 3-12, "Strain gauges are provided ... acceleration of the joint"). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the process of creating a stress-strain loop of Larsen with the computerized constructing method of Walker because it would provide for analyzing and evaluating the elastic component of joint stiffness to create the orthodic model based on the stress-strain loop.

Regarding claim 16

Walker teaches using data from said virtual human joint model as a basis to at least one of construct and adjust a physical orthodic for a user (col. 3 lines 16-20, "the process provides ... to duplicate it").

Regarding claim 17

Stark teaches using at least one of temperature, moisture, and skin conductivity sensors mounted on said joint-enclosed device (col. 2 lines 54-57, "Bladders spread the forces ... injury to the skin").

Regarding claim 18

Stark teaches data is received from a recording device associated with said sensors (col. 3 lines 10-14, "a microprocessor receiving ... predetermined target values").

Regarding claim 19

Stark teaches recording device is used to record said data during a period of use by a user of said joint-enclosing device, comprising downloading said recording data into said computer for analysis (col. 3 lines 10-14, "a microprocessor receiving … predetermined target values").

6. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker in view of Stark and further in view of Larsen and further in view of Applicant Admitted Prior Art (AAPA).

Regarding claim 3

Walker, Stark and Larsen teach a step of mapping stresses and accelerations experienced by a knee but do not teach using of interpolation techniques to analyze data over a period of time. However, AAPA teaches the use of interpolation techniques to analyze data over a period of time (specification, paragraph at the bottom of page 5, "One of ordinary skill … of the modeling process"). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the interpolation techniques of AAPA with the computerized method of Walker, Stark and Larsen because it would provide for analyzing sensory data with interpolation techniques in order to provide an optimal design for the virtual orthodic.

Regarding claim 4

Walker, Stark and Larsen teach a step of updating the virtual orthodic model using the map but do not teach the use of interpolation data to obtain an interpolated map. However, AAPA teaches the use of interpolation data to obtain an interpolated map (specification, paragraph at the bottom of page 5, "One of ordinary skill … of the modeling process"). Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to combine the interpolation techniques of AAPA with the computerized method of Walker, Stark and Larsen because it would provide for analyzing sensory data with interpolation techniques in order to provide an optimal design for the virtual orthodic.

Regarding claim 5

Walker, Stark and Larsen teach a virtual orthodic but do not teach the use of interpolation map to directly design the virtual orthodic in an optimal manner. However, AAPA teaches the use of interpolation map to directly design the virtual orthodic in an optimal manner (specification, paragraph at the bottom of page 5, "One of ordinary skill … of the modeling process"). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the interpolation techniques of AAPA with the computerized method of Walker, Stark and Larsen because it would provide for analyzing sensory data with interpolation techniques in order to provide an optimal design for the virtual orthodic.

7. Claims 6-7 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker in view of Stark and further in view of Larsen and further in view of Turner et al. U.S. Publication 2002/0072828 (hereinafter Turner).

Regarding claim 6

Walker, Stark and Larsen teach a method to model an orthodic but do not teach using non-linear techniques to optimize a model. However, Turner teaches using non-linear techniques for optimizing a model (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the non-linear technique for optimizing

a model of Turner with the human joint construction method of Walker, Stark and Larsen because it would provide for utilizing a constrained model to identify optimal set points for non-linear modeling of an orthodic.

Regarding claims 7 and 20

Turner teaches neural networks is used as a part of the modeling technique (page 7, paragraph 62).

8. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker in view of Stark and further in view of Larsen and further in view of Turner and further in view of AAPA.

Regarding claim 8

Walker, Stark, Larsen and Turner teach a method to model an orthodic but do not teach regression is used as a part of the modeling technique. However, AAPA teaches regression is used as a part of the modeling technique (specification, paragraph at the bottom of page 5, "One of ordinary skill ... of the modeling process"). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the regression technique for optimizing a model of AAPA with the human joint construction method of Walker, Stark, Larsen and Turner because it would provide for utilizing a constrained model to identify optimal set points for non-linear modeling of an orthodic.

Regarding claim 9

AAPA teaches expert systems or fuzzy logic is used as a part of the modeling technique (specification, paragraph at the bottom of page 5, "One of ordinary skill ... of the modeling process").

Response to Arguments

In the remark the applicant argues:

I) "no intent whatsoever in prior art (Stark) to use the pressure sensors to develop a force or pressure map to optimize adjustment, design, or construction of an orthodic" as to claim 1.

II) no teaching or "even suggests the calculation of a stress-and-acceleration map for joint orthodics" as to claim 1.

III) no suggestion in prior art (Stark) "using at least one of temperature, moisture, and skin conductivity sensors" as to claim 2.

IV) no suggestion in prior art (Wang) "... the use of interpolation techniques to analyze data over a period of time" as to claim 3.

In response to applicant's argument,

I) Applicant's amendment necessitated the new grounds of rejection that incorporate new prior arts (Walker et al U.S. Patent No. 4,936,862 and Larsen U.S. Patent No. 5,050,618) together with Stark. Walker teaches the computerized method of designing and constructing a virtual human joint for constructing other supporting devices for the joint. Larsen teaches the stress-strain loop based on collected sensors data. Stark teaches a microprocessor that analyzes data from pressure and acceleration sensors during actual operation of joint-enclosing device worn by a specific individual. The combination of Walker, Stark and Larsen teach a computerized method of **at least one of** designing, constructing, and adjusting an orthodic that use the pressure sensors to develop a force or pressure map for optimization. Therefore, limitations are met by combination of the references.

II) Larsen teaches (column 7 lines 63-65, "The large values of slope of the stress-strain loop at the end of the range of movement confirm the dominant contribution of elastic component of joint stiffness") a stress-strain loop for analyzing and evaluating the elastic component of joint stiffness based on sensors data. Thus, Examiner believes that the stress-strain loop is similar to the stress-and-acceleration map limitation since its data is based on continuous acceleration of the joint. Therefore, limitations are met by the reference.

III) Prior art (Stark) teaches (column 2 lines 54-57, "Bladder spread the forces over the patient's skin and provide a direct measure of the forces on the skin to provide a warning if the pressures reach a level that would cause injury to the skin"). Thus, according to claim 2, the "at least one of temperature, moisture, and skin conductivity sensors" is met by the "measure of the forces on the skin" as stated in Stark. Therefore, limitation are met by the reference.

IV) Applicant has admitted in the amendment to the bottom of page 5 in the specification ("One of ordinary skill in the art will recognize that various techniques … as part of the modeling process.") that the use of interpolation techniques to analyze data over a period of time is well known and expected. Therefore, limitations are met by Applicant Admitted Prior Art (AAPA).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Thomas Pham*; whose telephone number is (703) 305-7587 and fax number is (703) 746-8874. The examiner can normally be reached on Monday-Thursday and every other Friday from 7:30AM- 5:00PM EST or contact Supervisor, *Mr. Anil Khatri*, can be reached on *(703) 305-0282*.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-3900.

Thomas Pham
Patent Examiner

TP

December 23, 2003

ANIL KHATRI
SUPERVISORY PATENT EXAMINER